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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,522	03/09/2004	Joseph F. Poduslo	01017/30016A	2632
4743 7590 08/28/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 08/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/796,522	Applicant(s) PODUSLO ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31, 33-48 and 51-72 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 51-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31, 33-46, 48 and 67-72 is/are rejected.
- 7) ☒ Claim(s) 35 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/7</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 31, 48, 69-70 and 72 have been amended as requested in the amendment filed on June 13, 2007. Following the amendment, claims 31, 33-48 and 51-72 are pending in the instant application.

Claims 47 and 51-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claims 31, 33-46, 48 and 67-72 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on June 13, 2007 have been fully considered. New grounds of rejections are set forth below.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 31 and 42-45 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schenk, 1999, WO99/27944.

Applicant argues that “[a]ccording to Schenk, the A $\beta$  polypeptide or analog is used as a vaccine to treat CNS disorder; thus, any peptide fused to the A $\beta$  polypeptide or analog is not therapeutic” (p.8 of the Response). Applicant’s argument has been given careful consideration but it is unpersuasive that peptides of Schenk fused with A $\beta$  do not encompass polypeptides for treatment of CNS disorders. Since the class of molecules that are not A $\beta$  polypeptides is very broad and there are no real limitations disclosed in the instant specification as filed as to what is specifically included or excluded as defining non-polypeptides “for treatment of CNS disorders”, analogs of A $\beta$ , and fusion peptides of Schenk fully meet all the limitations of the instant claimed invention.

*New grounds of rejection necessitated by amendment*

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31, 33, 34, 42, 43, 48, 67-69 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al., 1997, Reference C4 of IDS submitted on August 07, 2007.

Claims 31, 33, 34, 42, 43, 48, 67-69 and 72 are directed to compositions comprising A $\beta$  polypeptide linked to a non-A $\beta$  polypeptide, which is a monoclonal antibody. Document of Wu et al. discloses such composition comprising A $\beta$  polypeptide (1-40) linked to a monoclonal antibody to the human insulin receptor. Since at p. 6 the instant specification specifically recites

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that non- A $\beta$  polypeptide could be any polypeptide and many polypeptides could be useful for treatment of CNS disorders, the limitations of the instant claims are met.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 36-41, 46 and 70-71 rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of Schenk.

Claims 36-41 recite compositions comprising amyloid polypeptide linked to an antibody, which is a monoclonal antibody, chimeric, humanized or a fragment. Publication of Wu et al. discloses linking of amyloid peptide to a monoclonal antibody. Since the art of antibody modification is well developed to produce and substitute a full size antibody for a fragment or a chimeric antibody and reasonably expect the same result of this procedure, the instant invention of claims 36-41 would have been obvious for one of ordinary skill in the art at the time of invention.

Further, claims 46 and 70-71 recite different modification within the known structure of amyloid peptide. Document of Schenk fully discloses analogs and mimetics of the amyloid polypeptide, which include substitutions of different amino acids as well as different length of the polypeptide (1-39, 1-40 or 1-42). Since publication of Wu et al. discloses linking of "normal" amyloid peptide to a monoclonal antibody and since substituting one amino acid with another one within the polypeptide sequence of A $\beta$  was fully disclosed in the art, it would have been obvious for a person of ordinary skill in the art to modify the composition of Wu et al. by changing the structure of A $\beta$  as indicated by Schenk and reasonably expect the resulting product to be the same.

***Allowable Subject Matter***

12. Claims 35 and 69 are directed to subject matter that is considered to be free of prior art and allowable if claims are rewritten in independent form. However, Applicant is advised that

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should claim 35, as amended, be found allowable, claim 69 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

13. Claims 31, 33-46, 48 and 67-72 are rejected, claims 35 and 69 are objected to.

14. Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 07, 2007, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

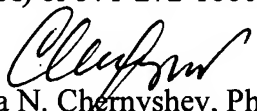
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

August 24, 2007